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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,125	11/21/2003	Franz Birke	1/1421	2235

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,125

Applicant(s)

BIRKE ET AL.

Examiner

Raymond J. Henley III

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-8 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 2, 3 AND 5-17 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed February 28, 2007 has been received and entered into the application. Accordingly, claims 1 and 4 have been canceled; claims 2, 3 and 5-13 have been amended; and claims 14-17 have been added.

Restriction/Election

As per the previous Office action dated August 31, 2006, claims 9-12 remain withdrawn from consideration under 37 C.F.R. § 1.142(b) as being directed to a non-elected invention. Claims 2, 3, 5-8 and 13-17 are herein acted on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection - 35 USC § 103

Claims 2, 3, 5-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderskewitz et al., (U.S. Patent No. 5,731,332, cited by Applicants) in view of Gregory et al., (U.S. Patent No. 6,172,096, cited by Applicants), each of record, for the reasons of record as set forth in the previous Office action dated August 31, 2006 as applied to claims 1-8 and 13, which reasons are here incorporated by reference.

The requirements of newly added claims 14-17 mirror previously presented claims 5-8 and thus have been considered.

Applicants' remarks at pages 8-10 of the above referenced amendment have been carefully considered, but fail to persuade the Examiner of error in maintaining this rejection.

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Insofar as Applicants have amended the claims to delete the compounds of formula (A2), (note previously presented claim 1), Schromm et al., (U.S. Patent No. 6,197,824, cited by Applicants) is no longer relevant and thus, has been removed as a reference against the present claims. This reference, however, nevertheless remains of record.

Applicants have traversed the present rejection on the basis that the prior art fails to teach or suggest the allegedly synergistic results shown in the present specification. Specifically, Applicants state that “[s]urprisingly, the claimed combination of LTB₄ antagonist and meloxicam show a synergistic effect, (page 16, lines 20-25 of the specification).

The Examiner acknowledges that the specification at page 16, lines 20-25 establishes a super-additive result which would not have been expected from the teachings of the prior art. The present claims, however, are not commensurate in scope with these results.

LTB₄ Antagonist Species and Dosages

The results in the specification are directed to a specific LTB₄ antagonist and meloxicam at specific dosages and not all claims are as limited, (see MPEP § 2144.08(II)(B)). A showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness *if* a skilled artisan “could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof” *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). Here, it has not been established that the single LTB₄ antagonist tested, (i.e., “1A”), provides a basis for concluding that all of the LTB₄ antagonists encompassed by the claims, (see

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claim 2), would behave the same. Similarly, it has not been established that the results for the single dosage amount tested for each compound would occur for the scope of dosage amounts/ratios allowed for in the present claims.

Composition Claims

The claims are further not commensurate in scope with the results in the specification because the results can only be obtained by practicing a method of reducing inflammation while the claims, because they are directed to compositions, are not so limited. This would also be true even if the present claims recited that the composition was useful for treating inflammation because this is merely a statement of intended use which does not provide any physical or otherwise material limitation.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

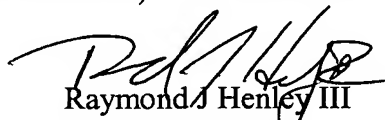
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Raymond J Henley III
Primary Examiner
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May 14, 2007